

Appl. No. : 10/020,140
Filed : December 14, 2001

REMARKS

This is in response to the Office Action mailed January 26, 2005. Claims 6-12 have been cancelled herein. Thus, Claims 1-5 and 13-20 are presented for examination. Applicant wishes to thank the Examiner for his review of the pending claims.

Discussion of Rejection under 35 U.S.C. §102(e)

The Examiner rejected Claims 1-5 and 13-20 under 35 U.S.C. §102(e) as being anticipated by Virtanen (6,342,349). The Examiner argued that Figures 2a-2f and 12 illustrate an embodiment that reads on the claimed invention. Applicant respectfully disagrees.

In order to apply a reference under 35 U.S.C. 102(e), the inventive entity of the pending application must be different than that of the reference (*See* MPEP 706.02(a)). In this case, the inventive entities are identical, in that the Applicant of the '349 patent and the Applicant of the present application are Jorma Virtanen. For this reason, Applicant respectfully requests withdrawal of this rejection.

However, even if the '349 patent was prior art to the present application, it still would not anticipate the claims. To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Applicant's invention relates to an optical disk based device that includes two units. In the first unit is an "amplification agent" that is produced upon contact with an analyte. That amplification agent then flows to the second unit. In the second unit the amplification agent is capable of changing a plurality of detection agents between a negative and a positive detection state. In one embodiment, the amplification reagent changes the strength of a plurality of reversible bonds that hold the detection agents. The amplification agent, for example, can be an enzyme or other catalytic compound which is capable of initiating and/or controlling numerous chemical reactions in the second unit (*See* specification, page 9, lines 20-21). As one example, the amplification agent can be DNA ligase. If analyte is present in the sample, the DNA ligase is

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released into the second unit where it fills in nicks on a *plurality* of DNA molecules that are bound to a plurality of detection agents. Thus, in a positive test, a single released DNA ligase results in multiple detection agents remaining bound to the disk. In contrast, in a negative test the nicked DNA chains in the second unit are broken and the detection agents become washed away. See the specification at page 12, beginning on line 21, and Figures 7 and 8 for a more complete description of this embodiment. The claimed system is advantageous in that a very small quantity of analyte can be detected since each analyte releases an amplification agent that catalyzes numerous reactions in the second unit.

The claimed device differs from that shown in the '349 patent in that there is no discussion in the '349 patent of releasing an agent that catalyzes a reaction on multiple detectors. Nor is there a teaching of an analyte detector unit and an amplification unit that are fluidly connected, as claimed. The assays shown in Figures 2a-2f as noted by the Examiner only teach a reaction where one analyte (a DNA) results in a measurable change in one detector. There is no teaching of DNA binding resulting in production of an amplification agent that goes on to change a plurality of detection agents. Indeed, what is being released in Figures 2a-2f is a metal microsphere which would not catalyze any type of further reaction.

For all of these reasons, the '349 patent does not teach each and every limitation of the pending claims. Thus, even if it was prior art, it would not anticipate the pending claims. For this reason, Applicant respectfully requests withdrawal of this rejection and allowance of the pending claims.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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